UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Braintree Laboratories Inc.,

Plaintiff,

–v–

Breckenridge Pharmaceutical, Inc.,

Defendant.

12-CV-6851 (AJN)

MEMORANDUM AND ORDER

ALISON J. NATHAN, District Judge:

Plaintiff Braintree Laboratories, Inc. ("Braintree") filed this patent infringement action on September 11, 2012. Dkt. No. 1. Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") filed its motion for summary judgment of non-infringement on July 6, 2015. Dkt. No. 84. For the reasons discussed below, Breckenridge's motion is GRANTED.

I. BACKGROUND[1]

This case arises from Breckenridge's attempt to obtain FDA approval for a generic version of Braintree's SUPREP, a colon cleansing solution. Braintree alleges that Breckenridge's product ("the Generic Product") infringes its patent, U.S. Patent No. 6,946,149 ("the '149 Patent").

A. The '149 Patent

The '149 Patent, issued in September 2005, is a composition and methods patent related to "colonic lavage," or colon cleansing. PCSMF ¶¶ 18-19, DCSMF ¶¶ 1-2. Claim 15 of the '149 Patent, as reexamined, recites:

[1] The following undisputed facts are taken from the parties' Stipulated Facts ("SF," Dkt. No. 86 Ex. T); Braintree's Counterstatement of Material Facts ("PCSMF," Dkt. No. 94), Breckenridge's Counterstatement of Material Facts ("DCSMF," Dkt. No. 99), or the underlying documents.

> A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 mL to about 500 mL of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

CSMF ¶ 26; Dkt. No. 86 Ex. G at 3. Similarly, claim 23 of the '149 Patent recites "[a] method for inducing colonic purgation in a patient . . . wherein the effective amount of the composition is administered in two or more doses within a treatment period." *Id.* at 4.

In the patent's specification, Braintree justified its invention by describing two main problems with existing methods of colonic lavage. PCSMF ¶ 19. On the one hand, the traditional method required consuming large quantities (approximately four liters) of solution. *Id.* While this method was "safe and efficacious," Braintree noted that "large volume solutions [were] not well tolerated by patients." *Id.* On the other hand, newer methods required "oral ingestion of small volumes of concentrated . . . solutions" but resulted in "clinically significant effects on bodily chemistry." *Id.* In this respect, the specification cited Fleet Phospho-Soda, which required taking "two (2) three ounce doses of [the solution], separated by a three to 12 hour interval for a total of six ounces (180 ml)." *Id.* ¶ 20. Braintree noted that this development represented "a significant reduction compared to the large 1 gallon volumes" of other products. *Id.* However, as noted in the specification, this treatment had "been shown to cause massive electrolyte and fluid shifts that are clinically significant to the patient." *Id.*

B. The Products

Braintree manufactures SUPREP, an osmotic laxative approved by the U.S. Food and Drug Administration ("FDA") for "cleansing of the colon in preparation for colonoscopy in adults." SF ¶¶ 1-4. SUPREP is sold as a kit containing two 6-ounce bottles of solution, each of which must be diluted with water to 16 ounces (473 ml) prior to consumption. *Id.* ¶¶ 5-6.

SUPREP's label instructs a patient to take one bottle of solution (diluted to 473 mL) the night before a scheduled colonoscopy, and the second bottle of solution (again diluted to 473 mL) ten to twelve hours later. *Id.* ¶¶ 27, 34-35, 41. Ingesting a single bottle of appropriately diluted solution causes a patient to have "copious, watery diarrhea." *Id.* ¶ 7.

Breckenridge's predecessor in interest, Cypress Pharmaceutical, Inc.,[2] sought approval from the FDA to market a generic version of SUPREP ("the Generic Product") through the Abbreviated New Drug Application ("ANDA") process. SF ¶¶ 9-10; *see also* 21 U.S.C. § 355(j) (describing the ANDA process); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1326-27 (Fed. Cir. 2003) (same). As required by the ANDA scheme, the Generic Product would be identical to SUPREP. SF ¶¶ 13-18; *see also* 21 U.S.C. § 355(j)(2); *Allergan*, 324 F.3d at 1326. As a result, the Generic Product would contain the same ingredients in the same quantities and be administered in the same manner as SUPREP. SF ¶¶ 13, 17, 28. If the ANDA were approved, the Generic Product would be sold as a kit of two 6-ounce bottles of solution, each of which must be diluted with water to 16 ounces (473 mL) prior to consumption approximately ten to twelve hours apart before a patient's colonoscopy. *Id.* ¶¶ 5-6, 13, 35, 41. As with SUPREP, drinking one appropriately diluted bottle of the Generic Product would cause a patient to have "copious, watery diarrhea." *Id.* ¶ 24.

C. Prior Braintree SUPREP Litigation

In 2011, Braintree filed suit in the District of New Jersey against Novel Laboratories, Inc. ("Novel"), another company seeking FDA approval for a generic version of SUPREP. DCSMF ¶ 84. Novel's generic version of SUPREP was identical to SUPREP, and as a result, to the

[2] In October 2013, the Court granted the parties' motion to substitute Breckenridge for Cypress Pharmaceutical Inc. Dkt. No. 62. For the sake of simplicity, the Court will refer to Breckenridge as the defendant when recounting the procedural history of even early stages of the case.

Generic Product in the instant litigation. *Id.* ¶ 85. In the *Novel* case, the district court construed certain terms of the patent, considered a number of non-infringement arguments advanced by Novel, and ultimately granted Braintree's motion for summary judgment of infringement. *Id.* ¶¶ 87, 90, 92-93; *see also Braintree Labs., Inc. v. Novel Labs., Inc.*, No. CIV.A. 11-1341 (PGS), 2012 WL 4120907 (D.N.J. Sept. 19, 2012) and *Braintree Labs., Inc. v. Novel Labs.*, Inc., No. CIV.A. 11-1341 (PGS), 2013 WL 211252 (D.N.J. Jan. 18, 2013) (together, "*Novel I*"). Novel appealed the district court's judgment to the Federal Circuit, which affirmed in part, reversed in part, and remanded to the district court for further proceedings. DCSMF ¶ 97; *see also Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1360 (Fed. Cir. 2014) ("*Novel II*"). The parties dispute to what extent the arguments currently raised by Breckenridge were raised by Novel on appeal and addressed by the Federal Circuit in *Novel II*. Br. at 3-6; Opp. Br. at 6-10.

D. The Instant Suit

In 2012, shortly after suing Novel, Braintree sued Breckenridge and alleged that its Generic Product infringed the '149 Patent. Dkt. No. 1. In February 2013, the parties indicated that the district court in *Novel I* had granted Braintree's motion for summary judgment of infringement. Dkt. No. 26. Thereafter, the parties entered into a stipulation to narrow the issues to be decided in this case. First, Breckenridge stipulated to the construction of the term "purgation" adopted by the District of New Jersey in *Novel I*.[3] Dkt. No. 41 ¶ 5; Dkt. No. 93 Ex. 1 at 23:1-4, 10-13. Under that construction, "purgation" is "an evacuation of a copious amount of stool from the bowels after oral administration of the solution." *Novel I*, 2012 WL 4120907, at *6. Breckenridge further stipulated that it would not present any argument "other than that based on the 'from about 100 mL to about 500 mL' limitation" in the '149 Patent. Dkt. No. 41 ¶

[3] After this stipulation was executed, the Federal Circuit affirmed the *Novel I* district court's construction of "purgation." *See Novel II*, 749 F.3d at 1355.

3. Bound by these stipulations, Breckenridge filed its first motion for summary judgment of non-infringement in July 2013. Dkt. No. 42.

In January 2014, the Court administratively denied the fully briefed motion and issued a stay in light of the pending Federal Circuit appeal in the *Novel* case. Dkt. No. 65. The Court lifted the stay in June 2015 but required Breckenridge to refile its motion "to account for developments in the *Novel* action as well as any developments in the law." Dkt. No. 80 at 3. Breckenridge filed the current motion for summary judgment of non-infringement on July 6, 2015. Dkt. No. 84. The parties' 2013 stipulation narrowing the issues to be decided continues to apply. Dkt. No. 41; Dkt. No. 80 at 3.

II. LEGAL STANDARD

Under 35 U.S.C. § 271(e)(2)(A), "[i]t [is] an act of infringement to submit [an ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent." Because this provision establishes patent infringement liability for ANDA applications related to generic "drug[s that] ha[ve] not yet been marketed[,] . . . the question of infringement must focus on what the ANDA applicant will likely market if its application is approved." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Section 271(b) further provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Under the inducement theory of patent liability, a drug manufacturer is liable when it induces doctors to prescribe or patients to use the infringing product. *Allergan*, 324 F.3d at 1328.

A patent infringement analysis has two steps: first, the court construes the patent claims as a matter of law, and second, the construed claims "are compared to the accused device." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). To successfully demonstrate infringement, "[a] plaintiff must establish by a preponderance of the

evidence that the accused device infringes one or more claims of the patent . . . literally."[4] *Id.* "Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s)." *Id.* "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Id.*

When evaluating a motion for summary judgment, the Court must "construe all evidence in the light most favorable to the non-moving party." *Ruggiero v. Cty. of Orange*, 467 F.3d 170, 173 (2d Cir. 2006). Granting such a motion is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[T]he burden is upon the moving party to demonstrate that no genuine issue respecting any material fact exists." *Gallo v. Prudential Residential Servs., Ltd. P'ship*, 22 F.3d 1219, 1223 (2d Cir. 1994). Thus, to justify summary judgment of non-infringement, Breckenridge must show that there is no "genuine issue of material fact with respect to the issue of literal infringement." *Bayer AG*, 212 F.3d at 1248.

III. DISCUSSION

In the present motion, Breckenridge contends that the Generic Product does not infringe the '149 Patent. Specifically, Breckenridge argues that the Generic Product does not satisfy the "from about 100 mL to about 500 mL" limitation of the patent because the product consists of 946 mL of solution. Relatedly, Breckenridge claims that the Generic Product does not violate § 271(e)(2) because the '149 Patent does not claim the FDA-approved use of the Generic Product. Braintree first responds that these arguments are barred by the Federal Circuit's decision in *Novel II*. Next, Braintree contends that these arguments involve claim construction, which the

[4] If literal infringement is absent, a product may still infringe a patent under the doctrine of equivalents. *Dawn Equip. Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1015 (Fed. Cir. 1998). Because Braintree has not raised the doctrine of equivalents as an alternative theory of infringement, the Court does not consider it.

parties stipulated not to address. Finally, Braintree argues that the Generic Product satisfies the volume limitation of the '149 Patent and violates § 271(e)(2). The Court addresses each of these arguments in turn.

A. Breckenridge's Non-Infringement Argument is Not Precluded by Binding Federal Circuit Law

As an initial matter, Braintree argues that the Federal Circuit rejected Breckenridge's non-infringement arguments in its *Novel II* decision. Opp. Br. at 8-10. Breckenridge responds that its arguments here were neither raised by the parties nor addressed by the majority in *Novel II*, and are thus not precluded by that decision. Br. at 4-6. To frame the analysis on this point, the Court must detail the history of this patent and the *Novel* case more fully.

As noted above, literal infringement requires "that the accused device contains each limitation of the asserted claim(s)." *Bayer AG*, 212 F.3d at 1247. The '149 Patent has four limitations: (1) it induces purgation of the colon; (2) it comprises from about 100 mL to about 500 mL of an aqueous hypertonic solution; (3) it comprises an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4; and (4) it does not produce clinically significant electrolyte shifts. *See* Dkt. No. 86 Ex. G at 1; *Novel I*, 2013 WL 211252, at *6-*10. In the *Novel* litigation, Braintree had to confront a potential problem: While the '149 Patent claims a "composition comprising from about 100 mL to about 500 mL of aqueous hypertonic solution," Dkt. No. 86 Ex. G. at 1, SUPREP and the Generic Product require administering a total of 946 mL of solution. SF ¶ 35. Faced with this issue, Braintree advanced a "one bottle" theory of infringement under which each appropriately diluted bottle of the Generic Product independently infringed the '149 Patent. Opp. Br. at 1. To prevail under that theory, Braintree needed to demonstrate that a single appropriately diluted bottle of the Generic

Product satisfied each of the four "limitation[s] of the asserted claim(s)." *Bayer AG*, 212 F.3d at 1247.

At the district court, Novel raised numerous arguments that one bottle of the Generic Product did not satisfy the various claim limitations. *See Novel I*, 2013 WL 211252, at *6-*10. Ultimately, the district court rejected these arguments and found one bottle of the Generic Product *did* infringe each limitation. *Id.* Novel did not appeal the district court's determination with respect to each limitation; instead, it appealed the proper construction of the terms "purgation" and "clinically significant electrolyte shifts" in the respective limitations.[5] *See* Dkt. No. 86 Ex. Q at 5-6; *Novel II*, 749 F.3d at 1352, 1354-55.

On appeal on the purgation issue, Novel argued that "purgation" was synonymous with "cleansing." Under such a construction, one bottle of the Generic Product would not satisfy the purgation limitation of the patent because two bottles of solution are necessary to cleanse the colon for a colonoscopy. Dkt. No. 91 ("Peura Decl.") ¶ 76. Ultimately, however, the Federal Circuit accepted the district court's construction of purgation as "an evacuation of a copious amount of stool from the bowels" instead of a full cleansing. *See Novel II*, 749 F.3d at 1354-55. As a result, the Federal Circuit held that a single bottle of the product satisfied the purgation limitation. *Id.* at 1356 ("[W]e likewise affirm the district court's finding that one (half-dose) bottle of SUPREP practices [the purgation] claim limitation.").

The majority in *Novel II* did not address whether one bottle of SUPREP satisfied the *separate volume limitation* of the patent, because Novel did not appeal that aspect of the district court's ruling. *See* Dkt. No. 86 Ex. Q at 5-6; *Novel II*, 749 F.3d at 1352, 1354-56. Braintree has repeatedly acknowledged that the arguments advanced by Breckenridge here were not raised by

[5] Novel also appealed the district court's determination on the validity of the patent and the construction of the term "a patient," neither of which is relevant here. *See* Dkt. No. 86 Ex. Q at 6; *Novel II*, 749 F.3d at 1352, 1357-58.

Novel on appeal and were thus waived. *See* Dkt. No. 68 at 3 ("Novel did not appeal the district court's rejection of [the 100 mL to 500 mL] noninfringement argument (and instead appealed the district court's infringement finding on other grounds). . . ."); Dkt. No. 86 Ex. R at 7 ("Although Novel claims to raise an 'unapproved use' argument . . . Novel did not raise that argument in its briefs to the panel, and therefore waived it."). Despite Novel's failure to appeal these issues, Braintree notes that the arguments now advanced by Breckenridge were raised *sua sponte* by Judge Dyk in a dissenting opinion. *See Novel II*, 749 F.3d at 1360-65 (Dyk, J., dissenting); Dkt. No. 68 at 3; Br. at 4; Opp. Br. at 9. Although the majority did not address these arguments, Braintree contends that the majority's holding in light of Judge Dyk's dissent demonstrates that "a majority of the panel rejected" these arguments. Opp. Br. at 10.

It is well settled that the Federal Circuit can exercise its discretion to consider an argument not raised in a party's opening brief but has no obligation to do so. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 n.9 (Fed. Cir. 2006). When it declines to exercise such discretion, it "assume[s] without deciding." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1294 (Fed. Cir. 2012). Braintree points to no authority suggesting that the Federal Circuit's failure to exercise its discretion to consider arguments not raised by the parties, even if raised *sua sponte* by the dissent, should be interpreted as a rejection of those arguments on the merits. As a result, the Court finds that the majority's silence is insufficient to conclude that Breckenridge's arguments are definitively precluded by Federal Circuit law.

B. Breckenridge's Non-Infringement Argument is Not Precluded by its Stipulation

As discussed above, the parties previously narrowed the issues to be resolved in this action. Dkt. No. 41. In their stipulation, the parties agreed that Breckenridge would "not [] present any defense of non-infringement . . . other than that based on the 'from about 100 mL to

about 500 mL' limitation." *Id.* ¶ 3. The parties further agreed that "the claim construction of 'purgation' adopted by the District Court in the *Novel* Case will apply." *Id.* ¶ 5. Braintree now argues that Breckenridge's motion "improperly reargues claim construction" despite having "stipulat[ed] that no claim construction is required" and "admitted that if this Court believes claim construction is necessary to resolve [the] motion, the case must be resolved in Braintree's favor." Opp. Br. at 12-13 & n.12.

As an initial matter, Braintree does not accurately represent what Breckenridge conveyed to the Court at the pre-motion conference. At that time, Breckenridge indicated that "if . . . *purgation* does need to be construed, then we will lose." Dkt. No. 93 Ex. 1 ("Tr.") at 10:19-20 (emphasis added). Pursuant to the stipulation, the Court will use the *Novel I* construction of "purgation," which was subsequently affirmed by the Federal Circuit in *Novel II*. Dkt. No. 41 ¶ 5; *Novel II*, 749 F.3d at 1355. Because purgation does not need to be construed, the Court need not resolve the motion in Braintree's favor on that ground.

Furthermore, contrary to Braintree's representation, the parties' stipulation does not provide that "no claim construction is required." Opp. Br. at 13. Instead, the stipulation indicates that Breckenridge "agrees not to present any defense of non-infringement . . . other than that based on the 'from about 100 mL to about 500 mL' limitation." Dkt. No. 41 ¶ 3. The language of the stipulation clearly contemplates the precise argument raised here: that the Generic Product fails to satisfy the volume claim limitation. This conclusion is further supported by Breckenridge's statements at the pre-motion conference previewing the argument it intended to make:

> The patent claim requires that the product be in the range of about 100 milliliters to about 500 milliliters. There's no dispute that we have 946 millilters. That's our defense. They say that you shouldn't

> count 946. You should only count the first bottle, which brings you under 500 milliliters, and, therefore, there's infringement."

Tr. 6:16-22. Braintree acknowledged this understanding of Breckenridge's intended argument in its June 2015 letter regarding the administrative hold in this case. *See* Dkt. No. 76 at 3.

It appears that Braintree's real concern with the volume limitation argument is that Breckenridge is "attempting to read a cleansing requirement into . . . 'from about 100 mL to about 500 mL'" and is thus indirectly challenging the construction of "purgation." Opp. Br. at 13. The Court considers the merits of Breckenridge's volume limitation argument below. At this juncture, however, it is clear from the pre-motion conference, the stipulation, and the letter motions on lifting the administrative hold in this case that the parties intended to litigate the "'from about 100 mL to about 500 mL' limitation" here.[6] Dkt. No. 41 ¶ 3; Tr. 6:16-22; Dkt. No. 75 at 3; Dkt. No. 76 at 3.

C. The Generic Product Does Not Infringe the '149 Patent

Because Breckenridge's arguments based on the "from about 100 mL to about 500 mL" limitation are neither precluded by Federal Circuit law nor barred by stipulation, the Court proceeds to consider the merits of Breckenridge's non-infringement arguments. Breckenridge's argument is best divided into two subparts, addressing the composition and method claims of the '149 Patent separately. With respect to the composition claims, Breckenridge argues that the Generic Product simply does not satisfy the volume limitation of the '149 Patent. With respect to the method claims, Breckenridge contends that there is no infringement under § 271(e)(2) because the method of use claimed in the patent is not the method of use for the Generic Product

[6] It is worth noting that Breckenridge raised the volume limitation argument in its pre-stay motion for summary judgment. Dkt. No. 43 at 14. At that time, Braintree did not argue that the parties' stipulation barred all construction of the "about 100 mL to about 500 ml" limitation. *Compare* Opp. Br. at 13, *with* Dkt. No. 48 at 10, 15. This reaffirms the Court's conclusion that the parties intended to litigate the issue.

approved by the FDA. The Court will first consider the composition claims argument and will then turn to the method claims argument.

1. Composition Claims: Volume Limitation

Braintree argues that the Generic Product infringes composition claims 15 and 18 of the '149 Patent. Opp. Br. at 3. Claim 15 of the '149 Patent recites "[a] composition for inducing purgation of the colon of a patient, *the composition comprising from about 100 mL to about 500 mL* of an aqueous hypertonic solution . . . ." Dkt. No. 86 Ex. G at 2 (emphasis added); PCSMF ¶ 35. Under its one bottle infringement theory, Braintree argues that one appropriately diluted bottle of the Generic Solution (half of the dose approved by the FDA) is a 473 mL solution and thus falls within the "from about 100 mL to about 500 mL" limitation. Opp. Br. at 12. Braintree further argues that the volume limitation modifies the purgation limitation; that is to say, that "from about 100 mL to about 500 mL" refers to the amount of solution required to induce purgation. *Id.* at 14. Breckenridge counters that the "from about 100 mL to about 500 mL" limitation refers not to a single bottle of the Generic Product or the amount of solution necessary to induce purgation, but instead to the entire volume of solution administered during the treatment period (*i.e.* 946 mL). Br. at 18-21. The district court in *Novel I* adopted Braintree's construction without significant discussion. *Novel I*, 2013 WL 211252, at *10. This Court is more persuaded by Breckenridge's argument.

The proper construction of patent claims is a question of law for the Court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). When a court construes the claims of a patent, "[i]t is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. . . . [T]he court starts [this] process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history." *Phillips v. AWH*

Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). For this reason, the specification is "highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The specification of the '149 Patent clearly demonstrates that the "from about 100 mL to about 500 mL" limitation refers to the entire volume of solution administered to a patient over a treatment period rather than the volume of a single bottle, or half-dose. This is apparent from the specification's description of experiments performed while developing the invention. *See* Dkt. No. 86 Ex. D at 5:57-61 ("90 mL [of Fleet Phospho-Soda] was added to 240 mL of water, for a volume of 330 mL. One half of this diluted solution was ingested by the subjects on two occasions."); *id.* at 5:64-6:3 ("The ingested experimental solutions were [] 330 mL in volume . . . . One half of each experimental solution was ingested by the subjects on two occasions, at 7 p.m. on day 1 and at 5 a.m. on day 2"). The fact that the specification repeatedly gives volume measurements as the total volume administered rather than the volume of a particular half-dose supports Breckenridge's construction of the "from about 100 mL to about 500 mL" limitation.

The prosecution history of the '149 Patent further confirms this understanding. In its request for patent reexamination, Braintree distinguished the prior art by comparing the "from about 100 mL to about 500 mL" volume claimed in its patent to larger volumes used in other colonic lavage products. *See* Dkt. No. 86 Ex. F at 10 ("Nor does Nissho disclose the use of about 100 mL to about 500 mL [of solution], rather Nissho discloses the use of 2 liters."); *id.* at 12 ("Nor does Martindale disclose the use of about 100 mL to about 500 mL [of solution], rather Martindale discloses the use of dilute solutions which implies about 4 liters of solution.").

Because these large volume solutions are not administered at one time but are instead administered in a series of partial doses, *see* Dkt. No. 86 Ex. D at 1:40-42, 53-56, such references suggest that "from about 100 mL to about 500 mL," like the 2 liter and 4 liter measurements to which it is compared, refers to the entire volume of solution administered to the patient.

Based on Braintree's use of volume measurements in the '149 Patent specification and its prosecution history, it would be clear to a "person of ordinary skill in the field of the invention," *Phillips*, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc.*, 133 F.3d at 1477), that the "from about 100 mL to about 500 mL" limitation refers to the total amount of solution administered to a patient over the treatment period rather than a single bottle, or half-dose. For this reason, the Generic Product, with a total volume of 946 mL, does not satisfy the volume limitation and thus does not infringe the composition claims of the '149 Patent.[7]

The parties agree that "the only independent claims of the '149 Patent are claims 2, 7, 15, and 18," all of which are composition claims. PCSMF ¶ 33; Dkt. No. 86 Ex. G at 1-3. The parties thus necessarily agree that method claims 19, 20, and 23, *see* Opp. Br. at 3, are dependent on these composition claims. Because the Generic Product does not infringe the independent composition claims of the '149 Patent, it cannot infringe the dependent method claims of the '149 Patent. *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) (quoting *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989)) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and

[7] As noted above, Braintree argues that this construction "read[s] a cleansing requirement into the claim term 'from about 100 ml to about 500 ml'" and thus challenges the construction of "purgation." Opp. Br. at 13. The Court's construction, drawing on the specification and prosecution history, makes clear that the volume limitation is distinct from the purgation limitation, whatever "purgation" means. As a result, neither Breckenridge's argument nor the Court's construction challenges the construction of "purgation" affirmed in *Novel II*.

thus containing all the limitations of) that claim."). The Court nevertheless considers Breckenridge's unapproved use arguments below.

2. Method Claims: Unapproved Use

Braintree argues that the Generic Product induces infringement of method claims 19, 20, and 23 of the '149 Patent. Opp. Br. at 3. Breckenridge responds that the Generic Product does not infringe these claims because it is FDA-approved for a method of use not covered by the patent. The Federal Circuit has repeatedly held that "a method of use patent holder may not sue an ANDA applicant [under § 271] for induced infringement of its patent[] if the ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use claimed in the patent is not FDA-approved." *Allergan,* 324 F.3d at 1332 (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-55 (Fed. Cir. 2003)). As the Federal Circuit has explained, "[t]he FDA-approved label for an approved drug indicates whether the FDA has approved a particular method of use for that drug." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1322 (Fed. Cir. 2012). The FDA-approval process "determines whether the information submitted with the application shows that the drug is safe and effective for the use described in the submitted label." *Id.*; *see also* § 355(d) (FDA approval requires showing that a "drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof" and that there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof"). Ultimately, FDA approval marks "the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." *Bayer Schering*, 676 F.3d at 1322.

It is undisputed that the "Indications and Usage" portion of the ANDA indicates that the Generic Product is "indicated for cleansing of the colon as a preparation for colonoscopy in adults." Dkt. No. 86 Ex. A. at 8. Breckenridge argues this FDA-approved use is distinct from the method claimed in the patent for inducing purgation. Br. at 23-24. Braintree responds that the *Warner-Lambert* line of cases targets "off-label" uses of drugs, and that using one bottle of the Generic Product to induce purgation is not an off-label use, but "the mechanism to achieve cleansing." Opp. Br. at 22, 24. In evaluating these arguments, the Court will separate claims 19 and 20 from claim 23.

a. Claims 19 and 20

In *Novel II*, the Federal Circuit accepted Braintree's argument that "purgation," defined as "an evacuation of a copious amount of stool from the bowels," was "something less than a full cleansing." 749 F.3d at 1354; *see also id.* at 1355 (contrasting purgation with "full cleansing" and the "fully cleansed colon for a colonoscopy"). This distinction was necessary for Braintree to meet the *purgation* limitation of the '149 Patent under its one-bottle infringement theory. *Id.* at 1354 ("[The one-bottle] infringement theory can prevail if purgation means . . . something less than a full cleansing."). Having successfully distinguished "purgation" from "cleansing," however, Braintree now faces another problem: The FDA-approved use of the Generic Product is "for *cleansing of the colon* as a preparation for colonoscopy in adults," Dkt. No. 86 Ex. A at 8 (emphasis added), while claims 19 and 20 recite "[a] method for *inducing colonic purgation* in a patient, comprising the steps of: (a) orally administering an effective amount of the composition . . . to a patient; and (b) allowing the administered composition to induce colonic purgation." Dkt. No. 86 Ex. G at 3 (emphasis added). In the face of Breckenridge's unapproved use argument, Braintree now argues that purgation is merely "the *mechanism* to achieve the *goal* of colon

cleansing" rather than a separate unapproved use. Opp. Br. at 21. This argument is unavailing, and an analogy used by Braintree before the district court in *Novel I* demonstrates why.

Braintree argued there that "using an asthma medication [to] improve[] breathing" would not be an unapproved use "if it works by reducing airway inflammation" because "reduction of airway inflammation is the method by which the medication achieves the goal of improved breathing." *Novel I*, 2013 WL 211252, at *9. In Braintree's asthma medication example, the "goal" is to improve a patient's breathing, and the "mechanism" for doing so is by reducing airway inflammation (*i.e.* targeting the cause of impaired breathing). In this situation, the degree to which a medication reduces airway inflammation is the degree to which that medication achieves the goal of improving a patient's breathing. As a result, such a medication cannot reduce airway inflammation without improving the patient's breathing if airway inflammation is the cause of the patient's difficulty breathing. Thus, in the asthma medication example, reducing airway inflammation is tantamount to improving patient breathing. In this situation, it would be sensible to conceptualize either improving breathing or reducing airway inflammation as the "goal" of the treatment.

Attempting to analogize, Braintree argues that the goal here is cleansing the colon, and that purgation is the method by which the Generic Product achieves the goal of colon cleansing. There is some facial appeal to this argument, because colloquially speaking, it seems intuitive that purging the colon is the method of achieving colon cleansing. However, the Federal Circuit's technical construction of "purgation" in light of Braintree's extensive efforts to distinguish "purgation" and "cleansing" ultimately dooms this analogy.

In *Novel II*, the Federal Circuit affirmed the district court's holding that "purgation" is the "evacuation of a *copious amount* of stool from the bowels" while "cleansing" was achieving the

"fully cleansed colon [required] for a colonoscopy." 749 F.3d at 1354-55 (emphasis added). The quantitative aspect of the Federal Circuit's construction is important because it transforms "purgation" from a colloquial method of achieving colon cleansing into "something less than a full cleansing." *Id.* at 1354. In other words, the Federal Circuit's definitions of "purgation" and "cleansing" locate those terms on different points on the spectrum of the colon-cleansing process. Under the Federal Circuit's construction, it is possible to induce purgation (that is to say, to "evacuat[e] a copious amount of stool from the bowels") without achieving the goal of full cleansing sufficient for a colonoscopy. As a result, it is possible to conceptualize the "evacuation of a copious amount of stool from the bowels" short of full cleansing as a distinct goal of treatment while it would be absurd to think of "reducing airway inflammation" as a distinct goal from improving breathing impeded by asthma.

This analysis demonstrates that "purgation" is not merely the "the *mechanism* to achieve the *goal* of colon cleansing," Opp. Br. at 21, but is instead some point on the colon cleansing spectrum short of "a full cleansing." *Novel II*, 749 F.3d at 1354 (describing purgation as "something less than a full cleansing"). Having successfully distinguished purgation and cleansing for its one-bottle infringement theory with respect to the purgation limitation, Braintree cannot now argue that purgation is tantamount to cleansing for the purposes of the method claims of the '149 Patent. Inducing purgation without "achieving a fully cleansed colon for a colonoscopy," *id.* at 1355, is not an FDA-approved use of the Generic Product, but is the method claimed in claims 19 and 20 of the '149 Patent. Because "the use claimed in the patent is not FDA-approved," the Generic Product does not induce infringement of claims 19 and 20 of the '149 Patent. *Allergan,* 324 F.3d at 1332 (citing *Warner-Lambert*, 316 F.3d at 1354-55).

b. Claim 23

The FDA does not regulate "use" only in terms of conditions that can be treated with a particular drug (or to use Braintree's terminology, the "goals" of treatment), but also regulates and approves "method[s] of use relating to the *dosage or method of administration* of a drug." *Bayer Schering*, 676 F.3d at 1323 (emphasis added). Thus, whether the '149 Patent and the Generic Product provide for the same "dosage or method of administration" is the key inquiry in evaluating Breckenridge's unapproved use argument with respect to claim 23. The "Dosage and Administration" portion of the Generic Product's ANDA indicates that "[t]he dose for colon cleansing requires administration of two bottles of [solution]. . . . Each bottle is administered as 16 oz of diluted . . . oral solution . . . ." Dkt. No. 86 Ex. A at 8. Thus, the FDA-approved dose is a total of 946 mL of solution, administered in a "split-dose" regimen of two 473 mL bottles of solution consumed over the course of ten to twelve hours. *Id.*

Braintree argues that claim 23 claims an identical method of administration. That claim recites "[a] method for inducing colonic purgation in a patient according to claim 20, wherein the effective amount of the composition is administered in two or more doses within a treatment period." Dkt. No. 86 Ex. G at 3. The district court in *Novel I* construed an "effective amount" to mean the amount of solution "necessary to produce a colonic purgation, while not producing clinically significant electrolyte shifts." *Novel I*, 2012 WL 4120907, at *6. Under this construction, which Braintree urges and Breckenridge does not contest, *see* Opp. Br. at 12 n.11; Dkt. No. 41 ¶¶ 3, 5, an "effective amount" of solution is 473 mL. SF ¶¶ 24-25. Thus, claim 23 covers the method of administering 473 mL of the solution "in two or more doses within a treatment period." Dkt. No. 86 Ex. G at 3.

Braintree argues that this language claims the method of administering the effective amount (*i.e.* 473 mL) "two or more *times* within a treatment period," for a total dose of at least 946 mL, consistent with the method of administration for the Generic Product. Opp. Br. at 12 n.11 (emphasis added). The plain language of the patent in the context of the specification belies this interpretation. As an initial matter, the method claimed in the '149 Patent is *not* administering the effective dose "two or more times" as Braintree argues, Opp. Br. at 12 n.11, but "in two or more doses within a treatment period." Dkt. No. 86 Ex. G. at 3. Braintree's resort to rewriting the claim in support of its position demonstrates the weakness of its proposed construction. The language of the specification further contradicts Braintree's position by specifically referencing "dividing" rather than multiplying the "effective amount" into doses. Dkt. No. 86 Ex. D at 5:19-24. ("Optimally, the effective dose may be *divided* and administered[] to the patient in two[] or more administrations over an appropriate time period.") (emphasis added). Braintree's expert even explains that, in the field of colonic lavage, developers had taken to "*splitting* the dose of the large volume isotonic preps, or administering *half the volume* of the large volume isotonic prep along with a stimulant laxative, to improve patient compliance." Dkt. No. 91 ¶ 46 (emphasis added). This makes clear that the patented method claimed in claim 23 is for dividing the "effective amount" (*i.e.* 473 mL) into two administrations of approximately 236 mL over a treatment period.

The above analysis demonstrates that the dosage and method of administration described in claim 23 are not the FDA-approved dosage and method of administration of the Generic Product. In sum, the FDA-approved dose for the Generic Product is 946 mL of solution administered in two half-doses, while claim 23 indicates that an "effective dose" of 473 mL of solution should be administered in two half-doses of approximately 236 mL. As Judge Dyk has

noted, "[a]n ANDA cannot infringe an asserted patent when the FDA-approved dose is not the dose claimed in the patent." *Novel II*, 749 F.3d at 1362 (Dyk, J., dissenting). For that reason, the Generic Product does not infringe claim 23 of the '149 Patent.

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The '149 Patent claims a composition with a total volume of from about 100 mL to 500 mL administered in two half-doses to induce purgation. The Generic Product has a total volume of 946 mL and is FDA-approved for administration in two half-doses of 473 mL for cleansing of the colon as a preparation for colonoscopy in adults. Because the Generic Product does not satisfy the "from about 100 mL to about 500 mL" volume limitation of the patent and "the use claimed in the patent is not FDA-approved," *Allergan*, 324 F.3d at 1332 (citing *Warner-Lambert*, 316 F.3d at 1354-55, the Generic Product does not infringe the '149 Patent.

IV. CONCLUSION

For the foregoing reasons, Breckenridge's motion for summary judgment of non-infringement is GRANTED. This resolves Dkt. No. 84. The Clerk of Court is instructed to terminate the case.

SO ORDERED.

Dated: March 15, 2016
New York, New York

ALISON J. NATHAN
United States District Judge